

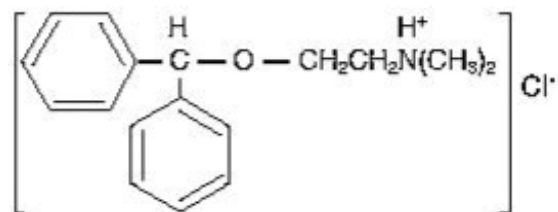
**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride injection, solution  
Fresenius Kabi USA, LLC**

**DiphenhydrAMINE Hydrochloride Injection, USP**

**Rx Only**

**DESCRIPTION**

Diphenhydramine hydrochloride is an antihistamine drug having the chemical name 2 (Diphenylmethoxy)-N,N-dimethylethylamine hydrochloride. It occurs as a white, crystalline powder, is freely soluble in water and alcohol and has a molecular weight of 291.82. The molecular formula is  $C_{17}H_{21}NO \cdot HCl$  and the structural formula is as follows:



Diphenhydramine hydrochloride in the parenteral form is a sterile, pyrogen-free solution. Each mL contains a concentration of 50 mg of diphenhydramine hydrochloride and water for injection, for intramuscular or intravenous use. The solution for parenteral use has been adjusted to a pH between 4 and 6.5 with either sodium hydroxide or hydrochloric acid.

**CLINICAL PHARMACOLOGY**

Diphenhydramine hydrochloride is an antihistamine with anticholinergic (drying) and sedative side effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells.

Diphenhydramine hydrochloride in the injectable form has a rapid onset of action. Diphenhydramine hydrochloride is widely distributed throughout the body, including the CNS. A portion of the drug is excreted unchanged in the urine, while the rest is metabolized via the liver. Detailed information on the pharmacokinetics of Diphenhydramine Hydrochloride Injection is not available.

**INDICATIONS AND USAGE**

Diphenhydramine hydrochloride in the injectable form is effective in adults and pediatric patients, other than premature infants and neonates, for the following conditions when diphenhydramine hydrochloride in the oral form is impractical.

**Antihistaminic:** For amelioration of allergic reactions to blood or plasma, in anaphylaxis as an adjunct to epinephrine and other standard measures after the acute symptoms have been controlled, and for other uncomplicated allergic conditions of the immediate type when oral therapy is impossible or contraindicated.

**Motion Sickness:** For active treatment of motion sickness.

**Antiparkinsonism:** For use in parkinsonism, when oral therapy is impossible or contraindicated, as follows: parkinsonism in the elderly who are unable to tolerate more potent agents; mild cases of parkinsonism in other age groups, and in other cases of parkinsonism in combination with centrally acting anticholinergic agents.

## CONTRAINDICATIONS

**Use in Neonates or Premature Infants:** This drug should *not* be used in neonates or premature infants.

**Use in Nursing Mothers:** Because of the higher risk of antihistamines for infants generally, and for neonates and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

**Use as a Local Anesthetic:** Because of the risk of local necrosis, this drug should not be used as a local anesthetic.

**Antihistamines are also contraindicated in the following conditions:**

Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

## WARNINGS

Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction.

Local necrosis has been associated with the use of subcutaneous or intradermal use of intravenous diphenhydramine.

**Use in Pediatric Patients:** In pediatric patients, especially, antihistamines in *overdosage* may cause hallucinations, convulsions, or death.

As in adults, antihistamines may diminish mental alertness in pediatric patients. In the young pediatric patient, particularly, they may produce excitation.

**Use in the Elderly (approximately 60 years or older):** Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

## PRECAUTIONS

**General:** Diphenhydramine hydrochloride has an atropine-like action and, therefore should be used with caution in patients with a history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease or hypertension. Use with caution in patients with lower respiratory disease including asthma.

**Information for Patients:** Patients taking diphenhydramine hydrochloride should be

advised that this drug may cause drowsiness and has an additive effect with alcohol.

Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

**Drug Interactions:** Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc).

MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals to determine mutagenic and carcinogenic potential have not been performed.

**Pregnancy: Pregnancy Category B:** Reproduction studies have been performed in rats and rabbits at doses up to 5 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to diphenhydramine hydrochloride. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Pediatric Use:** Diphenhydramine should not be used in neonates and premature infants (see CONTRAINDICATIONS).

Diphenhydramine may diminish mental alertness, or in the young pediatric patient, cause excitation. Overdosage may cause hallucinations, convulsions, or death (see WARNINGS and OVERDOSAGE).

See also DOSAGE AND ADMINISTRATION section.

## ADVERSE REACTIONS

**The most frequent adverse reactions are underscored:**

1. *General:* Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose, and throat.
2. *Cardiovascular System:* Hypotension, headache, palpitations, tachycardia, extrasystoles.
3. *Hematologic System:* Hemolytic anemia, thrombocytopenia, agranulocytosis.
4. *Nervous System:* Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions.
5. *GI System:* Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
6. *GU System:* Urinary frequency, difficult urination, urinary retention, early menses.
7. *Respiratory System:* Thickening of bronchial secretions, tightness of chest or throat and wheezing, nasal stuffiness.

## OVERDOSAGE

Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in pediatric patients. Atropine-like signs and symptoms; dry mouth; fixed, dilated pupils; flushing; and gastrointestinal symptoms

may also occur.

*Stimulants* should not be used.

Vasopressors may be used to treat hypotension.

## DOSAGE AND ADMINISTRATION

### THIS PRODUCT IS FOR INTRAVENOUS OR INTRAMUSCULAR ADMINISTRATION ONLY.

Diphenhydramine hydrochloride in the injectable form is indicated when the oral form is impractical.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT.

**Pediatric Patients, other than premature infants and neonates:** 5 mg/kg/24 hr or 150 mg/m<sup>2</sup>/24 hr. Maximum daily dosage is 300 mg. Divide into four doses, administered intravenously at a rate generally not exceeding 25 mg/min, or deep intramuscularly.

**Adults:** 10 mg to 50 mg intravenously at a rate generally not exceeding 25 mg/min, or deep intramuscularly, 100 mg if required; maximum daily dosage is 400 mg.

## HOW SUPPLIED

Diphenhydramine Hydrochloride Injection, USP is a clear and colorless solution available as:

Product Code	Unit of Sale	Strength	Each
RF787210	NDC 76045-235-10 Unit of 24	50 mg/mL in a 1 mL Prefilled Single-Use Syringe	NDC 76045-235-01 1 mL Prefilled Single- Use Syringe This Product Contains an RFID.
787210	NDC 76045-102-10 Unit of 24	50 mg/mL in a 1 mL Prefilled Single-Use Syringe	NDC 76045-102-00 1 mL Prefilled Single- Use Syringe

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature.]

Protect from freezing and light. Retain in carton until time of use.

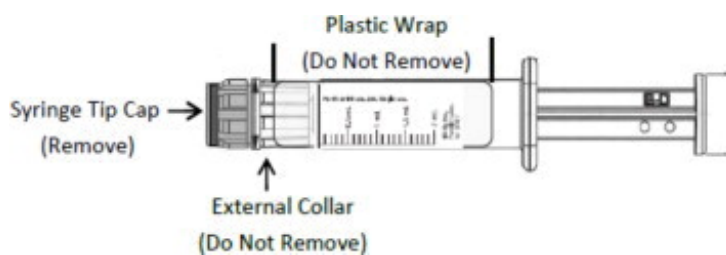
**Do not place syringe on a sterile field.**

## INSTRUCTIONS FOR USE

CAUTION: Certain glass syringes may malfunction, break or clog when connected to

some Needleless Luer Access Devices (NLADs) and needles. This syringe has a larger internal syringe tip and an external collar (luer collar). The external collar must remain attached to the syringe. Data show that the syringe achieves acceptable connections with the BD Eclipse™ Needle and the Terumo SurGuard2™ Safety Needle and with the following non-center post NLADs: Alaris SMARTSITE™, B-Braun ULTRASITE™, BD-Q SYTE™, Maximum MAX PLUS™, and B-Braun SAFSITE™. The data also show acceptable connections are achieved to the center post ICU Medical CLAVE™. However, spontaneous disconnection of this glass syringe from needles and NLADs with leakage of drug product may occur. Assure that the needle or NLAD is securely attached before beginning the injection. Visually inspect the glass syringe-needle or glass syringe -NLAD connection before and during drug administration. Do not remove the clear plastic wrap around the external collar. (See Figure 1)

Figure 1



1. Inspect the outer packaging (blister pack) by verifying:

- blister integrity
- drug name
- drug strength
- dose volume
- route of administration
- expiration date to be sure that the drug has not expired
- sterile field applicability

Do not use if package has been damaged.

2. Peel open the paper (top web) of the outer packaging that displays the product information to access the syringe. Do not pop syringe through.
3. Bend the plastic part of the outer packaging (thermoform) so as to present the plunger rod for syringe removal. (See Figure 2)

Figure 2

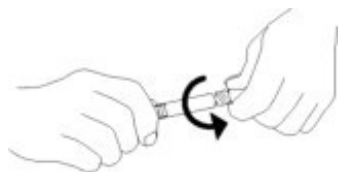


4. Perform visual inspection on the syringe by verifying:

- absence of syringe damage

- absence of external particles
  - absence of internal particles
  - proper drug color
  - expiration date to be sure that the drug has not expired
  - drug name
  - drug strength
  - dose volume
  - route of administration
  - integrity of the plastic wrap around the external collar
5. Do not remove plastic wrap around the external collar. Push plunger rod slightly to break the stopper loose while tip cap is still on.
  6. Do not remove plastic wrap around the external collar. Remove tip cap by twisting it off. (See Figure 3)

Figure 3



7. Discard the tip cap.
8. Expel air bubble.
9. Adjust dose into sterile material (if applicable).
10. Connect the syringe to appropriate injection connection depending on route of administration. Before injection, ensure that the syringe is securely attached to the needle or needleless luer access device (NLAD).
11. Depress plunger rod to deliver medication. Ensure that pressure is maintained on the plunger rod during the entire administration.
12. Remove syringe from NLAD (if applicable) and discard into appropriate receptacle. If delivering the medication with a needle, to prevent needle stick injuries, do not recap needle.

**NOTES:**

- - All steps must be done sequentially
- - **Do not autoclave syringe**
- - **Do not use this product on a sterile field**
- - Do not introduce any other fluid into the syringe at any time
- - This product is for single dose only

For more information concerning this drug, please call Fresenius Kabi USA, LLC at 1-800-551-7176.

**To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

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Lake Zurich, IL 60047

[www.fresenius-kabi.com/us](http://www.fresenius-kabi.com/us)

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Revised: November 2024

**PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine 1 mL Carton**

Rx only

NDC 76045-102-10

**DiphenhydrAMINE**

**HCl Injection, USP**

**HIGH POTENCY 50 mg per mL**

**For Intravenous or Intramuscular Use.**

**Do NOT place syringe on a Sterile Field.**

**24 x 1mL Prefilled**

**Single-use Syringes**

**Discard unused portion.**

www.fresenius-kabi.com/us

Single-use Syringes  
24 X 1 mL Prefilled  
For Intravenous or Intramuscular Use.

**Diphenhydramine**  
HCl Injection, USP  
**50** mg per mL  
HIGH POTENCY

NDC 76045-102-10

## DiphenhydrAMINE

### HCl Injection, USP HIGH POTENCY


# 50 mg per mL

**For Intravenous or Intramuscular Use.**

Each mL contains:  
Diphenhydramine hydrochloride 50 mg and water for injection, pH adjusted to 4.0 to 6.5 as necessary with hydrochloric acid and/or sodium hydroxide.

Usual Dosage: See package insert.  
Store at 20° to 25°C (68° to 77°F).  
[See USP Controlled Room Temperature].  
Protect from Light.  
Retain in carton until time of use.  
**Do NOT place syringe on a Sterile Field.**  
For more information concerning this drug product,  
call Fresenius Kabi USA, LLC at 1-800-551-7176.  
Fresenius Kabi Lake Zurich, IL 60047

Simplist<sup>®</sup>



(01)30376045102100

6215824

**DiphenhydrAMINE**  
HCl Injection, USP  
HIGH POTENCY  
**50** mg per mL  
For Intravenous or Intramuscular Use.

www.fresenius-kabi.com/us

Fresenius Kabi  
Lake Zurich, IL 60047

(01)30376045102100

6215824

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**DiphenhydrAMINE**  
HCl Injection, USP  
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www.fresenius-kabi.com/us

Fresenius Kabi  
Lake Zurich, IL 60047

(01)30376045102100

6215824

6215824

**DiphenhydrAMINE**  
HCl Injection, USP  
HIGH POTENCY  
**50** mg per mL  
For Intravenous or Intramuscular Use.

## PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine 1 mL Blister Pack Label

NDC 76045-102-00

**DiphenhydrAMINE**

**HCl Injection, USP**

**50 mg per mL HIGH POTENCY**

**1 mL Prefilled single use syringe.**

**Rx Only**

**For IV or IM use.**



NDC 76045-102-00

**DiphenhydrAMINE**  
**HCl Injection, USP**  
**50 mg per mL HIGH POTENCY**  
1 mL Prefilled single use syringe.  
Rx Only For IV or IM use.

**Read Instructions**  
Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature]  
Protect from light. Retain in Carton  
until time of use.  
Usual Dosage: See package insert.  
Do not place syringe on a Sterile Field.  
Discard unused portion.

**Simplist®**  
Fresenius Kabi

EXP YYYY-MM

LOT 0000000



(01)00376045102000

4 2 1 0 9 6

00

**PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine 1 mL Syringe Label**

1 mL Single-use For IV or IM use.

**DiphenhydrAMINE**

**HCl Injection, USP**

HIGH POTENCY, Rx Only **50 mg per mL**



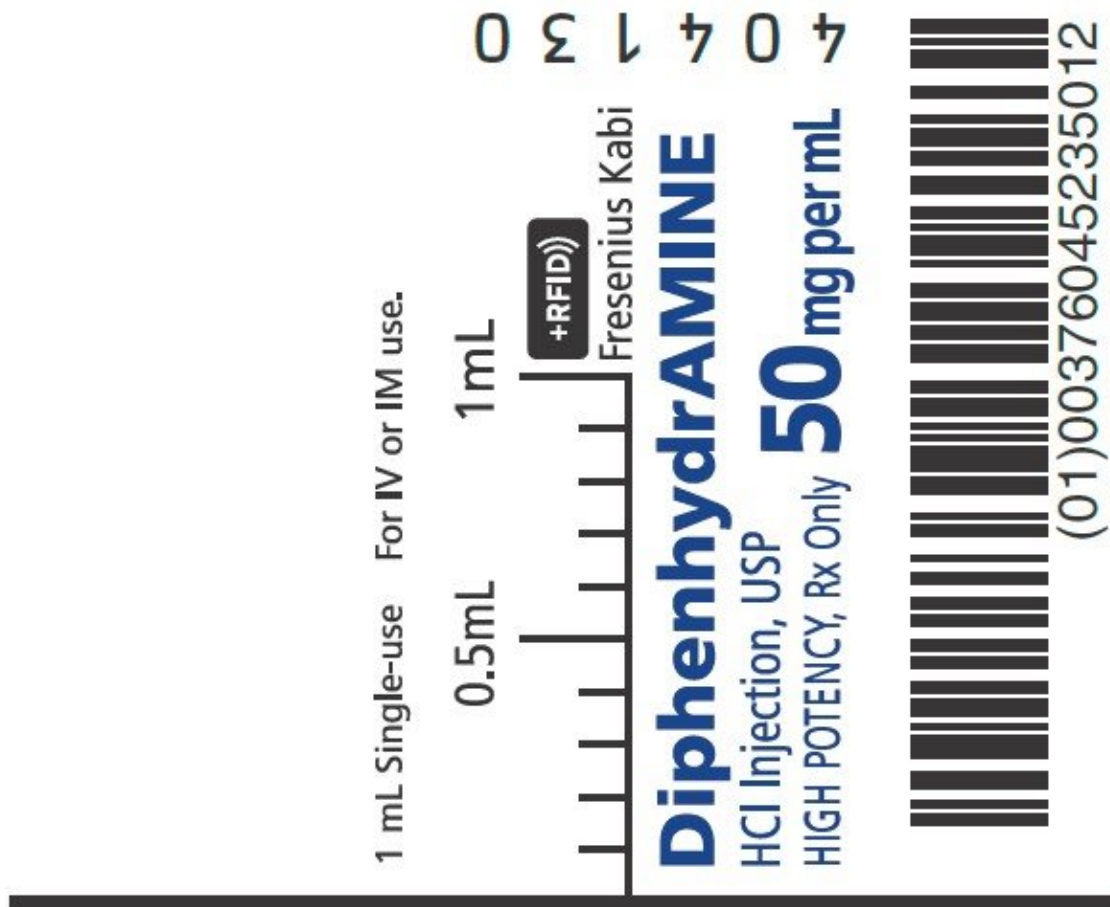
**PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine 1 mL Syringe Label**

1 mL Single-use                      For IV or IM use.

**DiphenhydrAMINE**

HCl Injection, USP

HIGH POTENCY, Rx Only   **50 mg per mL**



**PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine 1 mL Blister Pack Label**

NDC 76045-235-01

**DiphenhydrAMINE**

HCl Injection, USP

**50 mg per mL HIGH POTENCY**

**1 mL Prefilled single use syringe.**

**Rx Only**

**For IV or IM use.**

NDC 76045-235-01  
**DiphenhydrAMINE**  
**HCl Injection, USP**  
**50 mg per mL HIGH POTENCY**  
1 mL Prefilled single use syringe.  
Rx Only For IV or IM use.

**Read Instructions**

Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature]  
Protect from light. Retain in Carton  
until time of use.  
Usual Dosage: See package insert.  
Do not place syringe on a Sterile Field.  
Discard unused portion.

**Simplist®**  
+RFID  
Fresenius Kabi

EXP YYYY-MM  
LOT 0000000  
  
(01)00376045235012  
4 2 1 0 9 7 00

**PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine 1 mL Carton**

Rx only NDC 76045-235-10

**DiphenhydrAMINE**

**HCl Injection, USP**

**HIGH POTENCY 50 mg per mL**

**For Intravenous or Intramuscular Use.**

**Do NOT place syringe on a Sterile Field.**

**24 x 1mL Prefilled**  
**Single-use Syringes**

**Discard unused portion.**

NDC 76045-235-10  
**DiphenhydrAMINE**  
HCl Injection, USP  
HIGH POTENCY  
**50** mg per mL  
For Intravenous or Intramuscular Use.  
24 X 1 mL Prefilled  
Single-use Syringes

# DiphenhydrAMINE

HCl Injection, USP  
HIGH POTENCY **50** mg per mL

For Intravenous or Intramuscular Use.

Each mL contains:  
Diphenhydramine hydrochloride 50 mg and water for injection, pH adjusted to 4.0 to 6.5 as necessary with hydrochloric acid and/or sodium hydroxide.  
Usual Dosage: See package insert.  
Store at 20° to 25°C (68° to 77°F).  
[See USP Controlled Room Temperature].  
Protect from Light.  
Retain in carton until time of use.  
**Do NOT place syringe on a Sterile Field.**  
For more information concerning this drug product,  
call Fresenius Kabi USA, LLC at 1-800-551-7176.  
Fresenius Kabi Lake Zurich, IL 60047



621916

**DiphenhydrAMINE**  
HCl Injection, USP  
HIGH POTENCY  
**50** mg per mL  
For Intravenous or  
Intramuscular Use.



www.fresenius-kabi.com/us

www.fresenius-kabi.com/us

**DiphenhydrAMINE**  
HCl Injection, USP  
HIGH POTENCY  
**50** mg per mL  
For Intravenous or  
Intramuscular Use.

Rx only  
NDC 76045-235-10  
**DiphenhydrAMINE**  
HCl Injection, USP  
HIGH POTENCY  
**50** mg per mL  
For Intravenous or Intramuscular Use.  
Do NOT place syringe on a Sterile Field.  
24 X 1 mL Prefilled Single-use Syringes  
Discard unused portion.  
Simplist+  
Fresenius Kabi



## DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride injection, solution

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76045-102
Route of Administration	INTRAVENOUS, INTRAMUSCULAR		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 1 mL

Inactive Ingredients				
Ingredient Name			Strength	
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
HYDROCHLORIC ACID (UNII: QTT17582CB)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76045-102-10	24 in 1 CARTON	03/26/2013	
1	NDC:76045-102-00	1 in 1 BLISTER PACK		
1		1 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA091526	03/26/2013	

DIPHENHYDRAMINE HYDROCHLORIDE			
diphenhydramine hydrochloride injection, solution			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76045-235
Route of Administration	INTRAVENOUS, INTRAMUSCULAR		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
HYDROCHLORIC ACID (UNII: QTT17582CB)			
WATER (UNII: 059QF0KO0R)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76045-235-10	24 in 1 CARTON	06/02/2025	
1	NDC:76045-235-01	1 in 1 BLISTER PACK		
1		1 mL in 1 SYRINGE, GLASS; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091526	06/02/2025	

**Labeler** - Fresenius Kabi USA, LLC (608775388)

### Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi, USA LLC		964475045	ANALYSIS(76045-102, 76045-235) , MANUFACTURE(76045-102, 76045-235)

Revised: 4/2025

Fresenius Kabi USA, LLC